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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/575,429	05/22/2000	Jeffery A. Konecke	1002-111	2363
7590 01/04/2005				
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SAN DIEGO, CA 92121				
		EXAMINER		
		ALEXANDER, LYLE		
		ART UNIT		
		1743		
		PAPER NUMBER		
		DATE MAILED: 01/04/2005		

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/575,429

Applicant(s)

KONECKE, JEFFERY A.

Examiner

Lyle A Alexander

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2003.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-23 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Rejections - 35 USC § 112

Claims 2-4,9,10 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite as to what structure is intended by a "custom".

Claim 2 is vague and indefinite what orientation is intended by "back side" and "front side" because these orientations have not been defined relative to the cassette. Clarification could be achieved by describing the cassette as being received towards a front side of the cup and the back side being opposite the front side.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1,4-8,10 and 19-23 are rejected under 35 U.S.C. 102(b,e) as being clearly anticipated by WO 97/33519 (referenced as WO'97 hereafter) or Lapp(USP 5,916,815) respectively.

WO'97 teaches a test kit for the detection of common drugs of abuse that can be detected in urine samples. WO'97 teaches in figure 1 a transparent container(11), a sealed card(25) and slit means(19) to fit the container and the card. The container(11) has been read on the claimed "specimen cup", the sealed card(25) on the claimed "cassette" and the slit means(19) on the claimed "custom fit".

Similarly, Lapp teaches a drug detection kit with a collection cup(10), a test card(22) and in figure 2 the card(22) is attached to the lid(18) of the cup(10). The cup(10) has been read on the claimed "specimen cup", the card(22) on the claimed "cassette" and the attachment of the card(22) to the lid(18) on the claimed "custom fit".

With respect to claim 10, in light of the 35 USC 112 issues above, the means to prevent splashing have been read on the side walls of the container(11) and cup(10).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9 and 11-15 rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/33519 (referenced as WO'97 hereafter) or Lapp(USP 5,916,815) in view of Davis.

See WO 97/33519 (referenced as WO'97 hereafter) and Lapp(USP 5,916,815) *supra*.

These references are silent to the claimed slope of the container, the retracted flat face, a one-way flap to prevent spillage of the fluid, and the claimed polymer.

The court decided In re Boesch (205 USPQ 215) that optimization of a result effective variable is ordinarily within the skill of the art. A result effective variable has predictable and well-known results.

The degree of slop of the floor would have been a result effective variable to achieve the expected and well-known results speed of fluid travel and fluid pool depth created by the slope.

The orientation of the viewing face would have been a result effective variable to achieve the well-known and predictable results of bringing the results closer to permit better viewing by people with poor eye sight.

The use of a one-way valve is convention in the art of testing to prevent escape of test substance, which is potentially hazardous. Implementation of a one-way valve

would have been a result effective variable to gain the well-known and expected advantage of preventing the sample from contacting the technician.

It would have been within the skill of the art to modify WO 97/33519 (referenced as WO'97 hereafter) or Lapp(USP 5,916,815) and use a flat retracted face to bring the results closer to the viewer and use of a one-way valve as optimization of result effective variables.

The court decide In re Leshin (125 USPQ 416) that selection of a plastic based upon its suitability of intended use would have been within the skill of the art.

All of the claimed plastics are notoriously well known in the art and have the advantages of inertness, durability, lightweight, ability to be recycled and low cost of manufacture. It would have been within the skill of the art to modify WO 97/33519 (referenced as WO'97 hereafter) or Lapp(USP 5,916,815) and use the claimed plastic in view of Leshin above.

Allowable Subject Matter

Claims 2-3 and 16 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

Claims 17-18 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lyle A Alexander
Primary Examiner
Art Unit 1743
